

# Europäisches Patentamt European Patent Office Office européen des brevets



(1) Publication number:

0 420 450 A1

(12)

#### **EUROPEAN PATENT APPLICATION**

(1) Application number: 90309967.9

(51) Int. Cl.5: C12M 1/30

② Date of filing: 12.09.90

3 Priority: 18.09.89 NO 893706

(3) Date of publication of application: 03.04.91 Bulletin 91/14

Designated Contracting States:
 AT BE CH DE DK ES FR GB GR IT LI LU NL SE

Applicant: BIONOR A/S P O Box 1868 Gulset N-3701 Sklen(NO)

② Inventor: Hagen, Norman Gulsetkasa 5, 3700 Skien(NO)

Inventor: Kristiansen, Bjorn-Erik

Stromdalasen 60, 3700 Skien(NO)

Inventor: Sorensen, Birger

Tuyrveueb 37, 3700 Skien(NO)

Inventor: Kotlar, Hans Kristian

Hubroveien 8A, 3700 Skien(NO)

Representative: Allen, Oliver John Richard et al Lloyd Wise, Tregear & Co. Norman House 105-109 Strand London, WC2R 0AE(GB)

- (54) Collection and transportation device for microorganisms.
- (5) A collection and transport device for use by medical doctors, veterenarians and laboratory personnel, comprises a plastics tube (1) containing a culture medium, and closing means for the plastic tube. The closing means (2) is preferably provided with a retaining piece (5) for the shaft of a sample swab. The system is specially designed to provide a diffusion-resistant, unbreakable and transparent system. The tube and the closing means may be made from polyannide or polyethylene terephtalate.

2

#### COLLECTION AND TRANSPORTATION DEVICE FOR MICROORGANISMS

15

25

This invention relates to devices for the collection and transportation of microorganisms, for example for samples taken by or for medical doctors, veterinaries and laboratory personnel.

After a sample is taken, it is important that the microorganisms are kept alive and not permitted contact with any kind of contamination, extraneous matters and the like before the sample is taken for analysis and identification.

Samples of microorganisms are traditionally transported in a glass tube and sealed by a screw cork which is filled with a standard, sterile transport medium. To protect the glass tube against breakage and leakage, it is placed within a two piece plastic cover. To obtain the sample itself special sample swabs are utilised. This is a bulky and elaborate operation.

Therefore, other and more simple solutions have been proposed. One of these is described in US patent no. 3,450,129. The transport means of the invention of that patent consists of a unit in the form of a flexible plastics tube of polypropylene or the like with a removable lid which contains a separate glass ampulla filled with a sterile transport medium. The complete unit is covered by a protective seal made of plastic material.

When a sample is to be taken, the air-tight seal is broken and the lid with the swab is removed to collect a bacterium specimen. The lid with the swab is placed back in the tube and subsequently the glass ampulla is broken so that the swab is moistened by the culture medium. To ensure complete moistening the swab is in the form of an absorbent plug.

This device has gained wide utilisation in a number of countries but has a number of drawbacks. The glass ampulla can be broken accidentally, the sterile conditions are difficult to maintain after the original seal is broken and the device is complex and costly.

Another proposal for a safer collection and transport device is described in US patent no. 3.890,204. This construction consists of a sealed glass tube containing the culture medium and a separate lid carrying a sample swab. The two separate devices are packed together in a sealed package. The glass tube is air and gas-proof and closed at both ends. One of the ends is provided with indentations so that the end piece can be broken and the sample placed in the culture medium. When the sample has been taken the swab is placed inside the tube and the handle, which is also used as a lid, fits tightly around the tube to close it.

The glass tube is then placed back into the

original packaging and forwarded to the laboratory for analysis of the sample. With such a device the need for using an absorbent plug and an extra outer plastic tube as in US 3,450,129, is eliminated. However, this solution is not satisfactory either. The glass tube can easily break during transport and the cover or lid may not seal the tube satisfactorily.

Other solutions have been proposed to eliminate the drawbacks of using breakable glass ampullae. Thus it has been proposed to use soft plastics, such as polyolefins and polyurethanes. Such materials are of course unbreakable, but the softness creates problems under transport and handling. The culture medium may be displaced or even disappear from the tube. Furthermore, the plastic materials are not diffusion resistant so that a culture medium will be contaminated after a short period of exposure. So far, therefore, the use of glass tubes and glass ampullae has prevailed.

A collection and transportation device for cultures of microorganisms according to the invention comprises a vessel of plastics material for the keeping of a culture medium and closing means for the vessel, characterised in that the plastics vessel comprises an open-ended tube, of unbreakable, diffusion-resistant and transparent plastics material having a coefficient of permeability for  $O_2 < 300$ , and closing means also made of an unbreakable and diffusion-resistant material for sealing the open end of the tube, culture medium being provided within the tube. Such a device can be handled and transported without additional protection means.

The main tube is made of an impact-resistant. diffusion-resistant and transparent material, preferably polyamide or polyethylene terephtalate which are nearly diffusion-resistant for gasses like oxygen, nitrogen and carbon dioxide. Other suitable plastic materials which are also nearly diffusionresistant are polyvinylidenechloride and polyvinylfluoride or other materials which satisfy a permeability for O2 better or comparable to the above mentioned plastics. For instance, polyannide and polyethylene terephtalate are nearly 30 times as resistant to diffusion, at room temperature, than polyolefins. Plastics like polystyrene and polypropylene are on the other hand not applicable, having a coefficient of permeability which is 10-100 times higher than the aforementioned plastics. The plastic employed should have a permeability for oxygen at 25° which is lower than that which is limited by a permeability coefficient of :

13

### $P \times \frac{cm^{3}(NTP) \times 100\mu m}{m^{2} \times 24h \times bar} = 300,$

but preferably the coefficient should be below 30, to\_guarantee the complete durability and validity of the reduced medium.

The plastics used should, in addition, have a mechanical shock resistance better or comparable to the demands by DIN 53 453, which means that no breaks or marks are obtained when the material is subjected to an impact of 60KJ at 20 °C.

Such a microorganism collection and transport device has the advantages of easy availability and safe keeping of the culture medium under satisfactorily sterile conditions. It provides a simple and cheap construction which is unbreakable under normal circumstances and gives a safe and reliable protection without the danger of leakage of possibly pathogenic organisms after the samples have been collected.

The device is biologically safe, sterile and diffusion resistant under all conditions before, during and after the sample-taking procedure.

The device of the invention provides a tube which is permanently closed and in which the bacterium sample is completely covered by the culture medium when it is introduced into this medium by means of a sample swab. The system ensures the survival of both aerobic and anaerobic microorganisms.

The open end of the tube may be provided with external screw threads and the closing means with complementary internal screw threads. The closing means may also include means for retaining the upper end of the shaft of a swab, so that as the closing means is screwed onto the tube, the swab rotates within the culture medium, to provide complete covering of the swab with the culture medium.

Additional means may be provided around the open end of the tube to ensure a diffusion-tight seal. This means may comprise a surface which extends around the circumference of the tube, adjacent its open end, which co-operates with the bottom edge of the closing means. An O-ring may be provided between the abutting surfaces to improve further the seal.

The invention will now be further described with reference to the accompanying drawings in which: Figure 1 is a cross section of an example of a collection and transport device according to the invention; figure 1a is a detailed view of one end of the device shown in figure 1;

Figures 2a, b and c are schematic views of the device to illustrate how it is to be used.

The device comprises a tube 1 and a lid 2. The

open end of the tube 1 is provided with screw threads 7 and a collar 4 having an upper contact surface 3 for carrying a seal in the form of an Oring 8 or the like. A fitting lid 2 is provided with internal threads 9 and a central hollow end-piece 5 which can accept and retain the handle of a swab (see fig. 2b). The edge 6 of the lid is bevelled, giving it a sharp outer edge which will be pressed tightly into the O-ring 8 to form a diffusion-resistant seal when the lid is screwed on tightly. Complete diffusion sealage will be obtained when the lid is fastened manually (see fig.1a).

#### Examples for use of the transport device

The tube is filled with a suitable culture medium such as for example STARTS medium.

The sample swab, as shown in fig. 2a, comprises a breakable plastic handle or the like and a swab of absorbent cotton fibres. Each swab is provided in a separate breakable package and is sterile.

The sterile package is intended to be broken just before the sample is to be taken. During the sample-taking the tube will remain closed and sterile. When the sample has been collected, the screw lid of the tube is opened, the swab is inserted into the tube 1, the handle part of the sample swab is broken against the edge of the tube (as shown in fig. 2a) and the end is inserted into the end-piece 5 of the screw lid (as shown in fig.2b), after which the lid is screwed on tightly (see fig.2c).

This results in a rotating movement of the swab within the culture medium which will result in a complete covering of the swab so that when it is retracted to perform the final analysis, air or other contaminants would not have been able to enter.

In addition to the culture medium, the tube can be filled with an inert gas such as nitrogen.

The short time interval during which the tube will be open to the atmosphere, prevents the device from being contaminated by extraneous agents. When the lid or cork is tightened the tube is completely sealed. The tube is not susceptible to breakage and transportation can take place without special precautions.

The device is considerably improved as compared with prior known construction.

It is more hygienic, safer to transport due to the use of shock-resistant plastic, more durable due to its diffusion resistance, less bulky and suitable for use without outer protective packaging

The collection and transport device can be provided with a number of different culture media, both selective and universal. Also media which promote selective growth during transport can be

55

35

മവ

10

15

20

25

30

35

40

45

50

55

employed. Examples are:

- i) GC-media
- ii) Listeria media
- iii) ASTM-media for fungi
- iv) CBI for Clostridium fungi
- v) CLED for Coli bacteria
- vi) THIO-media for anaerobic fungus
- vii) etc.

#### Claims

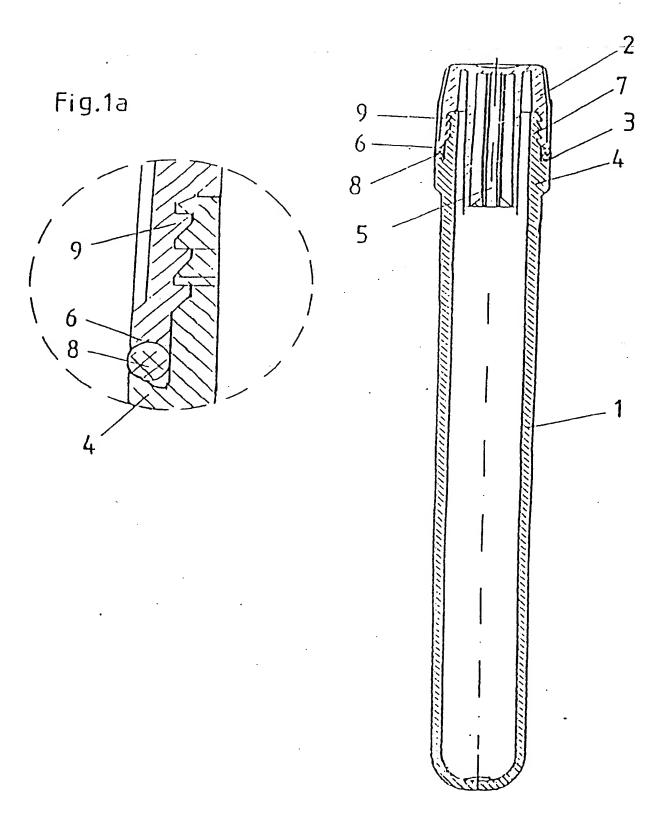
- 1. A collection and transportation device for cultures of microorganisms comprising a vessel of plastics material and closing means for the vessel, characterised in that the plastics vessel comprises an open-ended tube (1), of 'unbreakable', diffusion-resistant and transparent plastics material having a coefficient of permeability for  $O_2 < 300$ , and closing means (2) also made of an 'unbreakable' and diffusion-resistant material for sealing the open end of the tube, culture medium being provided within the tube.
- 2. A collection and transport device according to Claim 1 characterised in that the plastics material is polyamide or polyethylene terephtalate.
- 3. A collection and transportation device according to Claim 1 or 2 characterised in that the closing means (2) is adapted to retain part of a sample swab which is used for the gathering of a microorganism culture.
- 4. A collection and transport device according to any preceding claim characterised in that the open end of the tube (1) is provided with an external screw thread and the corresponding closing means with an internal screw thread and in that the closing means is provided with a central hollow retaining piece (5) which is designed to carry the upper end of the shaft of a swab whereby the swab is rotated into the culture medium when the closing means is tightened onto the tube (1).
- 5. A collection and transport device according to any preceding claim characterised in that the open end of the tube is provided with a collar (4) having an upper surface (3) which extends around the circumference of the tube and in that the collar (4) is designed for contact with the lower surface (6) of the closing means and with an intermediate sealing means (8).
- 6. A collection and transport device according to claim 5 characterised in that the lower circumference (6) of the closing means slopes inward and co-operates with an O-ring seal (8) placed against the contact surface (3) of the collar (4) which has a similar slope, thereby forming sharp contact edges which are pressed against the seal (8).
- A collection and transport device according to any preceding claim, characterised in that the plas-

tic tube is made of a plastic material with such high mechanical impact strength that no cracks are formed when the material is subjected to an impact force of 60KJ at 20°C.

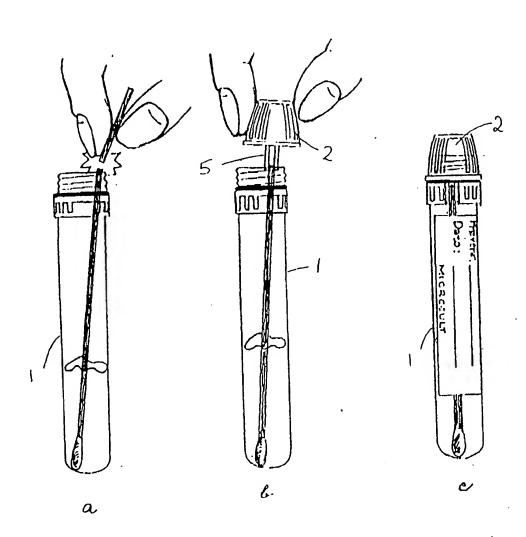
- 8. A collection and transport device according to any preceding claim characterised in that the plastic tube has an O<sub>2</sub> permeability coefficient < 30.</p>
- A collection and transport device according to any preceding claim characterised by properties which provide for survival of both aerobic and anaerobic microorganisms.

4

Fig.1



## Fig. 2





European Patent Office

#### EUROPEAN SEARCH REPORT

Application Number

EP 90 30 9967

DOCUMENTS CONSIDERED TO BE RELEVANT				
Category		th Indication, where appropriate, evant passages	Relev to ci	
Х	US-A-3 939 044 (T.D. WIL * Fig.; column 3, lines 1-8 *	KINS et al.)	1,3,7	-9 C 12 M 1/30
x	FR-A-2 612 297 (DIAGNOSTICS PASTEUR S.A.) * Cl. 1; page 5, lines 18-20; page 12, lines 31-32; figure 14 *		re 14 *	-9
A X	US-A-4 140 489 (SUN Y L * Cl.; fig.; column 3, lines 4-		6 1-2,7	-9
A	GB-A-9 451 90 (C.W. JINKINS) * Fig.; page 1, line 80 - page 2, line 47 *		1,3,4	
A	US-A-4 150 950 (M.M. TAKEGUCHI et al.) * Fig.; cl. 1; column 2, line 54 - column 3, line 19 *		1,3,4	₩.
А	US-A-3 913 564 (R.C. FRI * Fig. * —	ESHLEY)	1,3-5	. e,
				TECHNICAL FIELDS SEARCHED (Int. CI.5)
				C 12 M
				·
	The present search report has			
	Place of search Date of compl  The Hague 14 Jan			Examiner COUCKE A.O.M.
Y: [	CATEGORY OF CITED DOCI particularly relevant if taken alone particularly relevant if combined will document of the same catagory technological background non-written disclosure	UMENTS	E: earlier patent the filing date D: document cit L: document cit	document, but published on, or after seed in the application ed for other reasons
P: 1	non-written disclosure Intermediate document theory or principle underlying the ir	vention	document	e same patent tanny, corresponding

This Page Blank (uspto)